The Rapid Increase in Generic Prices in the UK: A Failure of Competition or Regulation?

Adrian Kay and Darrin Baines

There have been steep rises in the price of some generic drugs since September 1998. These rises have been the subject of an inquiry by the House of Commons Select Committee on Health. This article comments on the pricing of generic drugs and suggests possible solutions to the recent price rises. A fall in the price of generics in the five years prior to September 1998 was a result of regulatory action, rather than strong price competition. However, this regulatory system has now been shown not to have the incentives to encourage suppliers to meet the Government's objective of cheaper generic drugs. This raises the question of whether cost control strategies for primary care prescribing based on the greater use of generics are reasonable.

The control of pharmaceutical prices has been high on the agenda of most UK governments for the past two decades. There are obvious reasons for this. In an increasingly financially constrained National Health Service (NHS), the total drug budget has been rising by an average of 10% per annum (DoH, 1997). This increase has been due to a mixture or price and volume effects. Since 1978, the Pharmaceutical Price Regulation Scheme (PPRS) has regulated the price of branded drugs. The PPRS controls prices by capping the profits that manufacturers can make from the NHS. The PPRS was renegotiated in 1999 (DoH, 1999) and was the subject of an article in this journal (see Lawton, 1999). Although companies set the initial price of new products they introduce, they can only increase the price of their existing products with the permission of the Department of Health (DoH). However, in the market for generic drugs, manufacturers have complete pricing freedom and there is no PPRS-equivalent to limit the profits that manufacturers can make from NHS sales.

During the 1990s, both Conservative and Labour Governments have had strategies to increase the rate of the prescribing of generic drugs in NHS general practice. The Audit Commission identified increased generic prescribing as a means of making significant savings on the NHS drugs bill (Audit Commission, 1994). One effect of GP fundholding was to introduce a financial incentive to increase generic prescribing rates (DoH, 1989). The Labour Government has set Primary Care Groups (PCGs) the target of raising the national rate of generic prescribing to 72% (it was 63% in 1998) (Select Committee on Health, 1999). In addition, the new performance assessment framework document from the NHS Executive, *Quality and Performance in the NHS* (NHSE, 1999), lists generic prescribing as one of the 'high-level indicators of performance'.

These strategies have raised the share of generics in the NHS drugs bill from just over 11% in 1993 to almost 22% by the end of 1997 (Select Committee on Health, 1999). This article:

- Comments on the pricing of generic drugs and suggests possible solutions to the recent price rises. It describes and responds to the House of Commons Health Select Committee report into the generics market and the recent actions of the government.
- Outlines the implications for primary care prescribing.

The Pricing of Generic Drugs

The Select Committee report into the generics market, published on 21 December 1999, was triggered by a rapid rise in generic prices. Between September 1998 and September 1999, the cost of some generic drugs increased by over 700%. The price rises were demonstrated by a BBC *Newsnight* survey which suggested that, of 464 commonly prescribed generic drugs, 132 had increased in price by more than 50% in that 12 months.

One criticism of the Select Committee's report is that it concentrates too much on the headline percentage increases in certain generic prices. Table 1 shows that the largest percentage increases have been for those drugs that had the lowest prices in September 1998. The real issue for PCGs is how these increases affect the total

Adrian Kay is a lecturer in economics in the Business School at the University of Glamorgan. Previously, he worked as a government economist.

Darrin Baines is a senior lecturer in health economics in the University of Birmingham's Health Services Management Centre.

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Table 1. Cost for 28 days' supply of drug.

Drug name and strength	*Sep 1998*	*Sep 1999*	*Percentage increase Sep 1998–Sep 1999*
Frusemide 40 mg	26p	214p	723
Thyroxine 100 mg	21p	162p	670
Bendrofluazide 5 mg	15p	100p	567
Bendrofluazide 2.5 mg	15p	86p	473
Thyroxine 50 mg	19p	87p	360
Amoxicillin 250 mg (15)	47p	169p	260
Warfarin 5 mg	121p	276p	128
Warfarin 3 mg	82p	170p	107
Atenolol 50 mg	90p	146p	62
Atenolol 100 mg	122p	192p	57
Amoxicillin 125 mg/ml/100ml	91p	134p	48
Amoxicillin 250 mg/ml/100 ml	153p	225p	48
Aspirin 300 mg	12p	13p	8

Source: Based on Health Select Committee Report.

level of drug expenditure. For example, the problem with Bendrofluazide 5 mg is not a 567% increase but an 85p increase in price multiplied by the number of prescriptions dispensed.

The Market for Generics

Products with the same generic name and strength and of the same type of preparation can generally be dispensed interchangeably. Where a GP prescribes using a generic name, the pharmacist dispensing the prescription can use any version of the preparation that is licensed and meets the required specification (this is in contrast with the requirement for prescriptions written using brand names where only products with that brand name can be dispensed). This is supposed to allow generic products to compete on price at the point of dispensing. However, whether price competition will occur in the market for a particular generic drug depends on the number of suppliers of that drug.

A manufacturers' survey by the DoH shows that individual product markets have become more concentrated, as manufacturers have consolidated their activities on a smaller number of products. The very large price increases for generics have occurred in the most concentrated markets, where one or two manufacturers dominate supply. Most manufacturers supply drugs via wholesalers. Wholesalers can be divided into two main types:

- *Full-line* wholesalers, who keep a complete range of stock, and of whom there are a small number of national and regional players.
- *Short-line* wholesalers, who focus on a limited number of products and of whom there are a large number of companies of varying sizes.

In recent years the proportion of the generic market passing through full-line wholesalers has decreased, short-liners having expanded to take up a significant proportion of generic wholesale supply.

The Reimbursement System

There is a fixed-price reimbursement for dispensing pharmacists known as the 'Drug Tariff'. The fixed price was the average price of the drug charged by a basket of two major full-line wholesalers and three manufacturers. Membership of the basket is fixed. Prior to the Select Committee report, the DoH had always argued that this system encouraged competition, as there was an incentive for pharmacists to 'beat the mean' and buy lower than the reimbursement price. There is also a facility for the NHS to recover or 'clawback' the estimated discount that pharmacists receive. This is calculated through regular discount inquiries and aims to capture the extent to which they manage to buy at lower prices. Before generic prices started rising, the DoH had argued that this system provided an incentive for cost-effective purchasing and the NHS obtained the consequent financial benefits.

'Category D'

When either two wholesalers or one wholesaler and two manufacturers (from the basket) declare that they have less than four weeks supply of a drug it is placed in Category D. The pharmacist is then reimbursed the actual list price of the drug (which can be the price of the branded drug if that is what is dispensed), rather than the average basket price. The decision to place a drug on Category D is made by a negotiation between the DoH and the Pharmaceutical Services Negotiating Committee (PSNC).

For products in Category D, pharmacists do not have the same incentives to shop around; because they can be reimbursed at whatever price they pay. This system is designed to ensure

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that pharmacists are not penalized if they have to use more expensive sources to ensure patients do not go without their medicines. Although there have been significant price increases on other generics, the largest price increases have been in drugs that have been in category D. The number of drugs listed in Category D was 30 in September 1998 but by the end of 1999 it was approaching 200. Over the same period, Category D drugs have risen from 1% to 16% of the total number of prescriptions.

Recommendations

The main conclusion of the report is that the market for generics has been characterized by 'market manipulation, hoarding and collusion' (Select Committee on Health, 1999, para. 47). The current system for generic drugs 'has not only failed under the pressure of events but also actively contributed to the problems' (Select Committee Report, summary of conclusions).

Both recommendations of the report have been pre-empted. The Office of Fair Trading (OFT) is investigating the generics market for evidence of anti-competitive behaviour. And the Government has instigated its own wide-ranging review of the operation of the generics market to see if it requires revised or additional regulation or other, more fundamental, reforms. In addition, Lord Hunt has recently announced short-term measures to prevent the NHS being 'ripped off' (DoH, 2000). Under the proposals, there will be a statutory price ceiling for 15 months for the main generic medicines, corresponding to the average prices in the drug tariff for November 1998 to January 1999. These maximum prices will be reviewed after 15 months. At the same time, the Government is proposing changes to the reimbursement arrangements for pharmacists and dispensing doctors. In particular, this includes the abolition of the Category D arrangement in the drug tariff.

Discussion

A market is defined as the area within which consumers can readily substitute one good for another. There is not a single market for generic drugs; rather, there is a series of distinct markets for particular generics and their branded equivalents. A key characteristic of the markets for generics is that they are either oligopolies (there are a few supplies) or monopolies (there is only one supplier). Further, each generic market is a monopsony: the NHS is the only customer. Both monopsonies and oligopolies are characterized by market power, that is the ability to influence the outcome of the market. In each distinct market for generics, both customers and suppliers can influence prices and outputs (Gravelle and Rees, 1992).

A point made repeatedly in the Select Committee's Report is that the market in generics is a commodity market and therefore prone to fluctuations in price according to relative scarcity. The DoH's view was that, prior to recent events, the market in generic drugs had served the NHS well. John Denham, the Minister of State, told the Select Committee that 'the market did work for a long time effectively. It is not working effectively at the moment' (Select Committee on Health, 1999, para. 42).

The price of the top 65 most prescribed generics fell by about 15% between 1994 and 1998. However, this is not necessarily evidence of competition. In particular, there is no evidence of prices plunging towards cost levels. Further, the fall in prices is smooth and regular, quarter by quarter (Select Committee on Health, 1999, Annex C). In a competitive market, there would be much more volatility in the price even with a downward trend overall.

This article argues that the basket price system, rather than competitive forces, inspired the gradual fall in generic prices between 1994 and 1998. Prices fell incrementally as the reimbursement system and clawback mechanism encouraged pharmacists to seek small discounts. The fall in prices was in response to the regulatory regime rather than strong price competition.

There is no general theory of oligopoly in economics, but the key feature is that there is a strategic interdependence between the firms in the market. Each firm's price and output decisions affect everyone else. Because of this interdependence there is a strong incentive for firms to collude so as to avoid competition, to keep production low and prices high thus ensuring that profits are maximized.

However, economic theory suggests that this co-operation is difficult to achieve. In particular, it requires a mechanism or institution to share information about the actions of each firm. It may be argued that recently the Category D system has operated in such a way as to facilitate co-operation. The list of drugs in short supply (and therefore with a high price) has acted as a signal to manufacturers and wholesalers to maintain stocks at minimum levels, in order to keep the drug on Category D and, consequently, earn higher profits. The Select Committee's Report acknowledges genuine market reasons why certain drugs should have been in short supply at the beginning of 1999 (primarily the closure of a major manufacturer), but states there are no market reasons why they should have stayed on category D so long. This can be explained by strategic actions of firms to keep drugs on the list. It may be manufacturers in the basket with branded alternatives or wholesalers who are making higher profits from the supply of expensive Category D drugs or it may be large purchases by short-line wholesalers to prevent supply to full-line wholesalers in the basket. These are questions for the OFT investigation.

The problem with the current regulation for generics is that it is not 'strategy-proof' (Groves and Ledyard, 1987). It remains vulnerable to strategic actions by members of the basket of

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short-liners to keep prices high. This is not surprising. Any rational company will attempt to play the economic or regulatory system within which it operates to its best advantage. Therefore, the prime aim of any redesign of the pricing or regulatory system for generics is to make it immune to the strategic actions of those regulated.

Price volatility is a financial management problem for PCGs. The Select Committee's Report cites several examples of PCGs overspending their pharmaceutical budget due to the unpredicted steep rise in the price of generics. The issue for policy-makers is that the current system reduced generic prices between 1994 and 1998 and therefore saved the NHS money, but that this introduced price instability. A PPRS-like system would probably not have generated the past savings on drug costs, but it would have made them more controllable and therefore predictable. This is because the PPRS works as a profit control system, rather than specifying the price of individual drugs. In addition, the last two versions of the scheme negotiated in 1993 and 1999 have required all suppliers to reduce the average price of all their products covered by the scheme by 2.5% and 4.5% respectively. No price may be raised without the approval of the DoH.

Options for Change

Status Quo with Small Changes

There could be changes in the membership of the basket. The actions by manufacturers and wholesalers to increase prices, or to trigger Category D, tend to rely on the membership of the basket being fixed (and therefore making collusion easier). Regular changes to the basket may militate against such collusion. However, the production of most generic drugs would still be dominated by a small number of manufacturers. This basic structural feature of the markets for generics will still tend to make collusion more likely than competition whichever way the basket is constituted.

Extended PPRS

The PPRS could be extended to cover generics. As a price-cap system, it would have prevented the recent price rises. A major problem is that prices in the PPRS are capped at a high level in order to include a return on R&D expenditure, while generic manufacturers do not have any R&D expenditure. A variant would be a price ceiling for generics of the type proposed by the Government. The cost of such a system might be that some manufacturers cease production if the price ceiling is lower than the price that gives them an economic return. This may have the effect of reducing the supply of some generic drugs and create the problems that originally lead to the establishment of the category D system.

European Referencing

By adopting the logic that a generic drug is a commodity, it should be the same across Europe. Any redesign of the generic market could encourage pharmacists to source from the lowest cost producer in Europe. The basket of reference prices could be European instead of being based on five British companies. Other European countries include international prices for both their generic and branded drug price regimes, for example Belgium, the Netherlands, Ireland and Italy.

Conclusion

Policy towards the generic drugs market has fallen between two stools. There is no PPRS-like cap on prices or profits, and therefore prices can rise steeply. But neither are there enough generic manufacturers to replicate competitive market conditions. The price of generics has continued to be a function of the regulatory system and currently this is vulnerable to strategic actions by manufacturers and wholesalers to raise prices. This means that a PCG pharmaceutical budget based on a high rate of prescribing generically will sometimes be liable to overspend. Any reform of the current system for generics must be clear about its objectives. The options are to provide a stable price regime for generics through statutory regulation or, alternatively, to encourage price competition to achieve savings in PCG pharmaceutical budgets but with concomitant increase in price instability. ■

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